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(54) Title: AN IMPROVED METHOD FOR THE PREPARATION OF MONTELUKAST ACID AND SODIUM SALT THEREOF IN AMORPHOUS FORM

(57) Abstract: A method for the preparation of montelukast acid sodium salt thereof in amorphous form has been described. The method comprises of following steps: (a) generating the dilithium dianion of 1-(mercaptomethyl)cyclopropane acetic acid, by reacting with alkyl lithium, (b) coupling the said dianion with wet mesylate to get montelukast acid in crude form, (c) obtaining DCHA salt in crude form by adding dicyclohexylamine (DCHA) to crude acid obtained in the above step (b), (d) purifying and converting the said DCHA salt in crude form, to montelukast acid in pure form, and (e) reacting the pure montelukast acid in a polar protic solvent with a source of sodium ion followed by evaporating the solvent and triturating of the residue with non-polar water immiscible solvent.



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